

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 16

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MICHAEL E. FLAUGH

Appeal No. 1997-1954
Application 08/154,903

ON BRIEF

Before WINTERS and WILLIAM F. SMITH, Administrative Patent Judges, and
MCKELVEY, Senior Administrative Patent Judge.

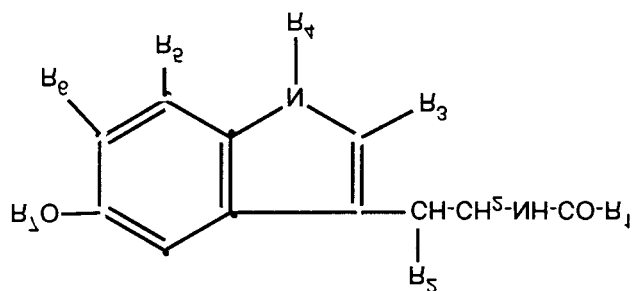
WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. §134 from the final rejection of claims
1 through 22, all the claims remaining in the application.

Claim 1 is representative of the claims on appeal and reads as follows:

1. A method of treating desynchronization disorders in a mammal suffering from or susceptible to such disorders which comprises administering to said mammal an effective amount of a compound of the formula



wherein

R¹ is hydrogen, C₁-C₄ alkyl or C₁-C₄ alkoxy;

R² is hydrogen or C₁-C₄ alkyl;

R³ is hydrogen, C₁-C₄ alkyl, phenyl or substituted phenyl;

R⁴ is hydrogen, haloacetyl, C₁-C₅ alkanoyl, benzoyl or benzoyl substituted with halo or methyl;

R⁵ and R⁶ are each independently hydrogen or halo; and

R⁷ is hydrogen or C₁-C₄ alkyl;

provided that when R² is hydrogen then at least one of R⁵ and R⁶ is halo.

The references relied upon by the examiner are:

Short et al. (Short)	4,600,723	July 15, 1986
Flaugh	4,997,845	March 5, 1991

An additional reference discussed by this merits panel is:

Frohn et al. (Frohn), "Structure-Activity Relationship of Melatonin Analogues," Life Sciences, Vol. 27, No. 22, pp. 2043-2046 (1980).

Claims 1 through 22 stand rejected under 35 U.S.C. § 112, first paragraph (enablement). Claims 1 through 22 also stand rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner relies upon Short and Flaugh. We reverse the rejection under 35 U.S.C. § 112, first paragraph, and vacate the rejection under 35 U.S.C. § 103. In addition, we raise other issues for the examiner to consider upon return of the application.

BACKGROUND

Melatonin is a known compound with several different uses, e.g., ovulation inhibitory activity, expedite recovery from “jet lag syndrome,” cause sleep, and minimize disturbances in circadian rhythms of bodily performance and function. See page 1 and lines 1-3 of page 2 in the specification. On page 13, lines 33-38, the specification incorporates by reference two patents which discuss desynchronized circadian rhythms and causes of the same including Short which is relied upon by the examiner in rejecting the claims under 35 U.S.C. § 103.

The claimed invention is directed to a method of treating desynchronization disorders in a mammal suffering or susceptible to such disorders which comprises administering to the mammal an effective amount of a compound having the formula as recited in claim 1. The claimed compounds can be termed analogs or derivatives of melatonin.

DISCUSSION

1. ENABLEMENT

The examiner has set forth two different reasons why the claims on appeal are non-enabled. The examiner first states on page 3 of the Examiner's Answer that "The specification does not teach or show what [sic, who] is susceptible to get the desynchronization disorders and does not show how the [sic] melatonin derivatives can treat a mammal susceptible to the disorders. Second, the examiner states in the paragraph bridging pages 3-4 of the Examiner's Answer that the disclosure is "enabling only for claims limited to treating the desynchronization disorders in a mammal with melatonin derivatives according to pages 1-21. The specification does not show enablement [sic] for treating the said disorders in a mammal susceptible [sic] to get the disorder."

The examiner has not begun to properly explain why a person skilled in the art would not be enabled to make and use the claimed invention. While we doubt that the examiner intends to require appellant to "limit" the claims to pages 1-21 of the specification that is what the examiner stated. Furthermore, it is clear that the examiner has limited his consideration of the issue to information provided in the specification but even that analysis is incomplete. For example, the specification incorporates Short by reference at page 13 for its discussion of the role melatonin can have in treating desynchronization disorders. As the examiner recognized in the obviousness rejection, Short also discusses the use of melatonin derivatives in treating such disorders. Yet the

examiner did not take such prior art knowledge into account in making his determination that the claims are non-enabled.

Determining enablement of a claimed invention by focussing on the specification of the application to the exclusion of the relevant prior art is legal error. “[A] specification need not disclose what is well known in the art.” Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997). Absent a fact-based statement of a rejection based upon the relevant legal standards, the examiner has not sustained his initial burden of establishing a prima facie case of non-enablement.

For these reasons, we reverse the examiner’s rejection of the claims under 35 U.S.C. § 112, first paragraph.

2. PRIOR ART REJECTION

In rejecting the claims the examiner states that Short teaches the use of melatonin for treating desynchronization disorders in mammals. The examiner also relies upon the passage of Short at column 7, lines 59-68 which reads as follows:

While the invention has been described with reference to the administration of melatonin, other related indoles or indole derivatives may be used. It has been shown that synthetic melatonin analogs do express varying degrees of melatonin agonist activity when tested on fish bioassay [citation of Frohn].

The examiner relies upon Flaugh as describing the melatonin derivatives required by the claims on appeal.¹ The examiner reasons that it would have been obvious to one of ordinary skill in the art at the time of the instant invention to treat desynchronization disorders using the melatonin derivatives taught by Flaugh since Short discloses in column 7, lines 59-68 that other melatonin analogs possessing the same activity as melatonin can be used to treat such disorders.

Our review of the record indicates that neither appellant nor the examiner have appreciated the full relevance of the passage found in column 7, lines 59-68 of Short. This passage refers to a publication by Frohn as describing the melatonin analogs which Short would consider useful in that invention. Neither appellant nor the examiner have retrieved and discussed this reference on the record. This is disappointing in that the claims on appeal require specific melatonin analogs, not just melatonin analogs in a functional sense.

While our disappointment extends to both the examiner and appellant in this regard, we are especially disappointed in appellant. Appellant (Appeal Brief, page 7) characterizes Short's disclosure of melatonin analogs which would be useful in that invention as being a "nebulous collection of compounds" or "unbounded." This is incorrect. Short refers to Frohn as describing specific melatonin analogs. We point out that

¹ The Flaugh patent appears to appellant's own work as both the patent and this application name Michael E. Flaugh as sole inventor and are commonly assigned.

appellant, in his previous patent relied upon by the examiner, discusses Frohn and distinguishes the melatonin analogs of Frohn from those described and claimed in his patent. See column 1, lines 38-45 of Flaugh. Why neither the examiner nor appellant took the time and effort to obtain and consider Frohn in this case can not be determined from this record. We have retrieved and evaluated Frohn and as one would suspect it is very relevant in determining the patentability of the claims on appeal.

Given the state of this record, we see no reason to expend the resources of the Board to determine whether the examiner's rejection of the claims under 35 U.S.C. § 103 is proper. Accordingly, we vacate the examiner's prior art rejection in lieu of the remand set forth below.

REMAND

1. SHORT AND FROHN

Frohn teaches that various melatonin analogs possess an activity similar to melatonin itself. Specifically, compound XVII described on page 2045 of Frohn appears to fall within the definition of the compounds used to treat desynchronization disorders according to the method recited in claims 1 through 4, 7 and 18 through 22. Since Short indicates that the melatonin analogs described in Frohn which have melatonin activity are useful in that invention, it would appear that the method set forth in these claims is at the least suggested by these two references.²

² Neither the examiner nor appellant have separately discussed the dosing schedule required by claims 18 through 22.

Appeal No. 1997-1954
Application 08/154,903

Upon return of the application to the examiner, the examiner should take a step back and re-evaluate Short and Frohn and determine if they adversely affect the patentability of claims 1 through 5, 7 and 18 through 22.

Appeal No. 1997-1954
Application 08/154,903

The remaining claims, claims 6 and 8 through 17, should be separately considered by the examiner in light of the disclosures of Short and Frohn. These claims require specific melatonin analogs. The examiner should consider the remaining melatonin analogs described by Frohn and determine whether they fall within the scope of the remaining claims.

REVERSED; REMANDED

Sherman D. Winters
Administrative Patent Judge

William F. Smith
Administrative Patent Judge

Fred E. McKelvey, Senior
Administrative Patent Judge

)
)
)
)
)
) BOARD OF PATENT
) APPEALS AND
)
) INTERFERENCES
)
)
)

WFS/cam

Appeal No. 1997-1954
Application 08/154,903

Eli Lilly and Company
Patent Division/DJT
Lilly Corporate Center
Indianapolis, IN 46285